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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,158	08/25/2003	Kenneth MC Cheung	V0690.0008/P008	3550

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EXAMINER

SHAFFER, RICHARD R

ART UNIT	PAPER NUMBER
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3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/648,158	Applicant(s) CHEUNG ET AL.	
	Examiner Richard R. Shaffer	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-22, 28, 29 and 32-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-22, 28, 29 and 32-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 20-22, 28, 29 and 32-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Sanders et al (US Patent 5,290,289).

Sanders et al disclose a method for correcting spinal deformities comprising: providing a correction force with a Nitinol (a material with superelastic, pseudoelastic, and shape memory properties) rod (**Column 5, Lines 50-65**), which can apply some correction during surgery. The rod is first pre-contoured to assume normal kyphosis and lordosis (**Column 5, Lines 50-55**) and then deformed to conform to the spinal deformities. The rod is capable of having the force adjusted by remotely heating the rod with a radio frequency induction heater (**Column 7, Lines 55-60**). The heating allows for individual adjustment of the rod sections for corrective force. In regard to claims 28 and 29, anterior and posterior can relate to any direction as broadly recited, and when considering **Figure 2**, it is clear that the rod does apply force to a side of the vertebra.

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Anchor members (bone clamps and blockers; **Column 3, Line 5 through Column 4, Line 11**) are utilized to limit the rod from rotational movement and are made of Nitinol.

Claims 20-22, 28, 29 and 32-43 rejected under 35 U.S.C. 102(b) as being anticipated by Cool et al (European Patent Application 0 470 660 A1).

Cool et al disclose a method for correcting spinal deformities comprising: providing a correction force with a Ti-Ni (1:1 ratio so it is Nitinol) alloy rod (**Column 4, Lines 54-55**) having various cross-sections (i.e. square, rectangular) and various transition temperatures which can adjust the force applied; a force is present operatively by the inherent process of placing the spine and device in alignment; the prolonged corrective force is activated by the body's own heat (**Column 1, Line 1 through Column 2, Line 26**) which would activate during the procedure. The rod is pre-formed to match the spinal rod (**Column 3, Lines 27-59**) and deformed to conform to the spinal deformity (**Column 3, Lines 20-26**) in order to be fixed by anchors (6), which act to limit the correction device from rotational movement. Again, in regard to claims 28 and 29, anterior and posterior can relate to any direction as broadly recited.

Claims 20-22, 28, 29, and 32-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Drewry et al (US Patent 6,783,527).

Drewry et al disclose a method for correcting spinal deformities comprising: providing a correction force through the use of tethers (80) made of Nitinol (**Column 3, Lines 60-65**) which is inherently activated by heat; the forces activated during surgery and are adjusted/set by tensioning the tethers (80) by the surgeon. The tethers (80) are anchored by elements (30 and 50) that are formed of Nitinol (**Column 4, Line 66**

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through Column 5, Line 6) which limit rotational movement of the tether. The overall device can be placed anteriorly or posteriorly (**Column 3, Lines 48-55**). The device is deformed to conformed to the spinal deformities (inherent due to it being tensioned and anchored to the vertebrae).

Response to Arguments

Applicant's arguments filed November 20th, 2006 have been fully considered but they are not persuasive.

Applicants assert that Sanders et al do not provide a correction force by a superelastic material. Because Nitinol exhibits superelasticity, pseudoelasticity (transformational superelasticity), and shape memory, it is clearly a "superelastic material." In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., applicant's device not requiring heating) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In regard to Sanders et al supposedly not disclosing a "constant force," again the limitation is not found in the claim, however applicant does use "maintain the correction force." Sanders et al clearly maintain a correction force once it has been deemed proper by the physician. It does not matter if the physician gradually increases the force until the "correction force" is achieved and "maintained."

In regard to applicant's arguments to Cool et al, as explained, Nitinol is material with superelastic properties. Further, if given broadest reasonable interpretation, since

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pseudoelasticity is also referred to as transformation superelasticity, some amount of superelasticity is still present in both Sanders et al and Cool et al as applicant argues.

In regard to Drewry et al, applicant states that Drewry et al is silent as to whether a constant or substantially constant force is disclosed. Again, applicant is directed towards the non-claimed limitation that his argument relies upon, but further is informed that since the tether (80) is effectively a spring, it is an inherent physical property to which springs act with a constant force. Therefore while not explicitly stating a constant force, it is clearly inherent of the device.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Richard Shaffer
January 31st, 2007


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER